



Analysis of Impurities From a Pharmaceutical Drug with New OROSIL ODS HPLC Column

Dr. Sunil Dhuri and Dr. Asha Oroskar, Orochem Technologies Inc.

Analyzing residual impurities of varied properties in pharmaceutical drug is a challenging task to the analyst. Reversed Phase Liquid Chromatography (RP-HPLC) is known to be one of the most effective methods for analyzing the pharmaceutical drugs of complex composition. To separate large number of impurities of different nature and properties requires various technical approaches and instrumentation.

The choice of the appropriate chromatographic techniques requires understanding of the retention mechanisms and molecular interactions of chromatographic system components. In addition to the mobile phase, sample molecular interactions, stationary phase - analyte and stationary phase - mobile phase interactions are very important. Particularly, the interactions between components of varied characteristics of retention in these complicated systems.

New Orosil ODS stationary phase developed by OROCHEM TECHNOLOGY INC. offers wide range of selectivity's for organic molecules of different nature and properties. Proprietary bonding and end capping mechanism in Orosil ODS yields better peak shape for acidic, basic and neutral compounds. Also Orosil ODS offers better selectivity's for varied range of polar to non polar components.

Method & Experimental Conditions:

A high-performance liquid chromatographic (HPLC) method was developed for the analysis of a pharmaceutical drug and its 49 related impurities in bulk drug using Orosil ODS HPLC column. This method has shown good resolution for known and unknown impurities on Orosil ODS 250-4.6 mm, 5 μ m column. Mobile phase was prepared using methanol and acetonitrile and phosphate buffer systems with pH 3.0. Samples were eluted under gradient with the mobile phase at flow rate 1.0 ml min^{-1} and detected at 254 nm. 20 μ l sample was injected. Analysis was performed under similar experimental conditions using Inertsil ODS 3 250-4.6 mm, 5 μ m column and results were compared.

Results & Discussion

Though the physical properties such as surface area, pore volume of Orosil ODS & Inertsil ODS 3 are different, resolution obtained using a Orosil ODS column (Fig 1) is relatively superior compared to Intersil ODS 3 250-4.6mm, 5 μ m column (Fig 2). In addition to improved selectivity for polar and non polar components, Orosil ODS offers wide range of pH stability (pH 1.5 to 9) compared to Inertsil ODS-3.

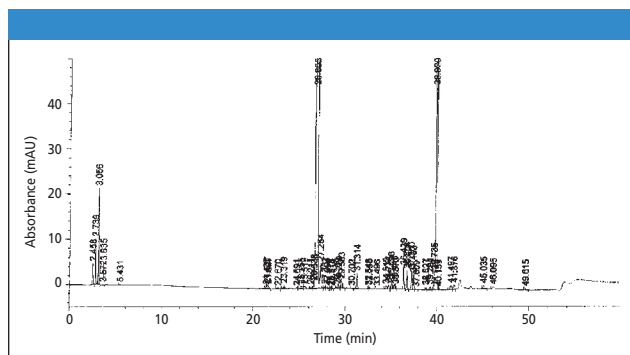


Figure 1: Analysis on Orosil ODS 250-4.6 mm, 5 μ m.

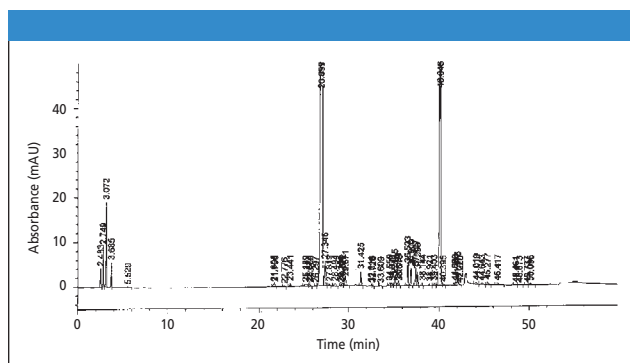


Figure 2: Analysis on Inertsil ODS 3 250-4.6 mm, 5 μ m.

Orochem Technologies Inc,

Einshower Ln South, Lombard, IL 60148

Tel: 630-916-0225

www.orochem.com